Amendments to the Specification:

In the Title:

Change the title from "Whole Body Stereotactic Localization System" to -- "Whole Body Stereotactic Localization and Immobilization System"

In the Specification:

On page 1, line 15, delete the one sentence paragraph and insert the following:

--The present invention relates to medical equipment and methods, more particularly to equipment and methods for radiation therapy including stereotactic localization and immobilization systems and methods.—

A1

On page 3, delete lines 22 through 27, and insert the following:

--As noted by Bentel and Marks (Bentel, et al. 1997) and Bentel (Bentel 1999), a number of methods have been historically used for patient immobilization during radiation therapy. More recently the concept of stereotactic localization, which has previously been successfully applied to radiotherapy/radiosurgery of the brain (see Lutz, et al. 1988), has been applied to extracranial radiotherapy target areas. (Lax 1994, Lederman 1998, and Hamilton, et al., 1995 [1990] and 1997).--

A2

Delete the paragraph starting at page 6, line 27 through line 9 on page 7, and insert the following:

--The present invention is of a system for use in the field of medicine and primarily for fractionated stereotactic radiotherapy / radiosurgery and other stereotactic procedures. The system is an external whole body immobilization and stereotactic localizer system. The term 'whole body' refers to all or some portion of the body of the patient. The term 'stereotactic localization system" as used in the art of stereotactic treatment particularly of the patient's brain, generally includes some means for immobilizing the patient's cranium and is thus part of the 'stereotactic localization system'; however, in this application the term 'whole body immobilization' system is used as a complement to the 'stereotactic localization system;' the two systems comprise the present invention. It gives a high degree of precision target localization for whole body stereotactic procedures including biopsy and radiotherapy with a unique imaging resolver fiducial localization method. As noted above, the need for effective patient immobilization has become widely recognized in recent years, particularly as the application of conformal radiation treatment techniques (where small treatment margins are possible) has increased. (Bentel, 1999 pp. 23-38). Stereotactic conformal radiotherapy with dose escalation to the targeted lesion is improved with this accurate and reproducible target localization system. Head, neck, thoracic, abdominal, or pelvic localization is possible with the present invention, which may be extended to include the entire body.--

A3

On page 7, delete the paragraph beginning at line 12 through line 21, and insert the following:

--The present invention is of a body immobilization and stereotactic localization frame and method comprising use of a non-invasive device for immobilizing a human body from head to pelvis comprising form fitting custom molds for both anterior and posterior portions of the body. In the preferred embodiment, the posterior mold is a vacuum mold or polyurethane foam mold and the anterior mold is a thermoplastic mold, both being reusable over the course of a fractionation or other treatment regimen for the subject patient. The [base] frame comprises one or more imaging localization fiducials wherein one of the fiducials varies its position along an axis of the frame depending on position in another axis of the frame. Quality assurance markers are placed in opposing pairs at predetermined positions along an axis of the frame. An imaging resolver (as later defined) is preferably supplied comprising a continuous array of coupled fiducials.--

Delete the paragraph beginning on page 7, line 23 and ending on page 8, line 2, and insert the following:

-- The present invention is also of a stereotactic localization frame and method employing an imaging resolver (as subsequently defined) comprising a continuous array of coupled fiducials. In the preferred embodiment, one or more imaging localization fiducials have a waveform that depends on position in an axis of the frame, preferably a trigonometric wave form such as a sine or cosine waveform, and most preferably coupled fiducials are provided forming a $\pi/2$ horizontal linked sine and cosine wave fiducial pattern. A non-invasive device for immobilizing a human body from head to pelvis is employed comprising form fitting custom molds for both anterior and posterior portions of the body. Quality assurance markers are placed in opposing pairs at predetermined positions along an axis of the frame.--

On page 9, delete the first paragraph and insert the following:

-- The localization features of most stereotactic frames are similar, differing mainly in the organization of the coordinate system of the frame and its mechanical dimensions. All stereotactic frames are created for the purpose of immobilization, precise patient repositioning, and localization of volume structures or lesions within the volumetric space defined by the frame and the immobilized body part. With regards to stereotactic frames, the general convention is that the long axis of the body (longitudinal [transverse] axis) is given the designation [of] as the z-axis in the Cartesian coordinate system of three-dimensional spatial localization. The left-right axis is generally designated as the x-axis and the anterior/posterior axis is designated as the y-axis. Most conventional stereotactic frames use incremental indicators in millimeters and centimeters along each axis for precise coordinate referencing. The aim of the stereotactic frame system of the present invention is to permit a wide area of body immobilization and allow precise stereotactic imaging and positioning of body areas within the frame.--

On page 11, delete the paragraph beginning on line 20 through line 25, and insert the following:

--The invention permits aligning and imaging a body part by immobilizing the body part within a stereotactic body localization system having an imaging resolver fiducial localizer for precise imaging and localization of the body parts within the apparatus. The system comprises a [base frame] frame including a base and sides with an imaging localization fiducial arrangement (imaging resolver) embedded in its base and sides. The base frame is preferably manufactured from polycarbonate, or other durable and versatile thermoplastic or similar material having a low radiation beam attenuation.—

On page 12, delete the paragraph beginning on line 14 through line 24, and insert the following:

--The present invention improves upon the less versatile localizers manufactured by Elekta Instrument AB and Howmedica (Leibinger). The Elekta Stereotactic Body Frame™ is limited to treatment of targets in the abdominal, thoracic and pelvic regions and uses a saltatorial, non-continuous fiducial arrangement having limited accuracy with a high incidence of undetectable errors. The Elekta system is non-invasive but does not handle procedures on the head and neck. Immobilization is achieved by the limited use of a vacuum mold for posterior immobilization only (that portion of the body nearest the frame's base). (Precision Therapy brochure 1995, Lax, et al., 1994a and b and 1998, and Näslund, et al., 1997). An uncomfortable breastplate must be used with pressure against the sternum for reduction of diaphragmatic movements. The Howmedica (Leibinger) system uses a substantially equivalent method of immobilization, but requires an invasive method for spinal fixation (Hamilton, et al., 1995 [1990] and 1997).--

On page 14, delete the paragraph beginning at line 14 and ending at line 20, and insert the following:

--Fig. 10 illustrates the preferred fiducial geometry of the invention with preferred fiducials **1,2,3,4,5,6,7,8**. The central three fiducials **4,5,6** constitute the imaging localization resolver along the z-axis. The arrangement comprises:

a) an origin as marked by the circle with the quadrants;

b) a centrally placed diagonal fiducial **5** the position and slope of which is mathematically defined as x = 70 - 0.08z, located between;

c) a cosine wave fiducial **4** which is defined as x=-70+40cos((z/250)*360°); and

d) a sine wave fiducial **6** which is defined as x=120-0.08z-40sin((z/250) *360°).

The position and specific waveforms of the fiducials 4, 5 and 6 should be understood to be merely exemplary of the preferred fiducial geometry of the invention.--

Delete the paragraph beginning on page 15, line 20 and ending on page 16, line 3, and insert the following:

--For purposes of the specification and claims, an "imaging resolver" is an array of imaging fiducials arranged in a mathematically predictable pattern that permits the calculation of finer incremental resolution along another fiducial pattern, such fiducial patterns being used to define a multi-dimensional data set and portions thereof. An imaging resolver can be used to more precisely locate positions in a three-dimensional volumetric data set (stereotactic space) or a two-dimensional data set such as obtained from imaging with scanning devices such as CT, MRI, and like imaging systems used to define or sample a three-dimensional data set. An imaging resolver is preferably positioned in an instrument about a patient's body and multi-dimensional image data sets can represent portions of the patient's body. The imaging resolver of the invention comprises a continuous array of coupled fiducials, avoiding the difficulties and inaccuracies inherent in the use of phantom simulators (Hamilton, et al., 1995) and in non-continuous, saltatorial, or serially recurrent [fidicuial] fiducial patterns such as found in prior art devices like that defined by Onik, et al., (U.S. Patent No. 4,583,538) and Lax, et al., 1994.—

Delete the paragraph beginning on page 16, line 5 through line 19, and insert the following (the last line is appropriately bracketed, no deletion is intended]:

-- Referring to Fig. 11, illustrating the preferred resolver decoding method of the invention, all fiducials referred to are preferably on the anterior surface of the base of the frame of the invention. The term "angle" (Θ) refers to a quantity which varies linearly over the length of the device, from a value of zero at Z=0mm to a value of 9π at Z=1125mm. The sine and cosine of this quantity are represented by the sine and cosine fiducials, respectively. RHS refers to the Right-Hand Side of the frame of the invention, and LHS refers to the Left-Hand Side. CRT refers to a Cathode Ray Tube (refers to measurements made on the CRT screen and expressed in pixel units.) The constants shown are:

X0 = 100 [nominal distance between RHS and diagonal fiducials at Z=0 (mm)]
S0 = 50 [nominal distance between diagonal and sine fiducials at Z=0 (mm)]
C0 = 60 [nominal distance between LHS and cosine fiducials at Z=0 (mm)]
Wnom = 300 [nominal distance between LHS and RHS fiducials (mm)]
Slope = .08 [nominal slope of diagonal fiducial (mm/mm)]
Pitch = 250 [nominal pitch of [sinusioids] sinusoids (mm/cycle)]
Amp = 40 [nominal amplitude of sinusoids (mm)]
Thetaslope = Slope*Pitch/(2 π) [slope of diagonal fiducial versus angle (mm/radian)]--